

## **4X MEDICATED SEVERE TOOTHACHE AND GUM GEL- benzocaine gel**

### **Rite Aid**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----

### **Active Ingredients Purpose**

Benzalkonium Chloride 0.13% .... Oral Antiseptic  
Benzocaine 20% ..... Oral Pain Reliever  
Menthol 0.5% ..... Oral Pain Reliever  
Zinc Chloride 0.15% ..... Oral Astringent

### **Use**

Use \* for the temporary relief of pain due to toothaches \* to help protect against infection of minor oral irritation

### **Warnings**

Methemoglobinemia warning: use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in the blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops: \* pale, gray, or blue colored skin (cyanosis) \* headache \* rapid heart rate \* shortness of breath \* dizziness or lightheadedness \* fatigue or lack of energy

### **Allergy Alert**

do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

Do not use \* more than directed \* for more than 7 days unless told to do so by a dentist or doctor \* for teething \* in children under 2 years of age

Stop use and ask a doctor if \* swelling, rash or fever develops \* irritation, pain or redness persists or worsens \* symptoms do not improve in 7 days \* allergic reaction occurs

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

### **Directions**

\* cut open tip of tube to score mark \* adults and children 2 years of age and older: apply a small amount of product to the cavity and around the gum surrounding the teeth. Use up to 4 times daily or as directed by a dentist or doctor \* children under 12 years of age should be supervised in the use of this product \* children under 2 years of age: do not use

### **Other Information**

Other information \* do not use if tip is cut prior to using \* this preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist can be consulted \* do not use continuously \* this formula will stay in place for extended duration of relief \* avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying

ammonium glycyrrhizate, blue 1, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid

LORNAMEAD  
 1.031 X 1.031 X 3.500 - PRINTSIDE  
 SBS S170273 - 3/6/17



LORNAMEAD, INC.		PROJECT INFO   PRODUCTION NOTES			
DATE:	APRIL 27, 2020	<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"><span style="background-color: cyan; width: 15px; height: 15px; display: inline-block;"></span> CYAN</div> <div style="text-align: center;"><span style="background-color: magenta; width: 15px; height: 15px; display: inline-block;"></span> MAGENTA</div> <div style="text-align: center;"><span style="background-color: yellow; width: 15px; height: 15px; display: inline-block;"></span> YELLOW</div> <div style="text-align: center;"><span style="background-color: black; width: 15px; height: 15px; display: inline-block;"></span> BLACK</div> </div>	<b>APPROVALS</b>		
PROJECT:	RITE AID 4X MEDICATED TOOTHACHE GEL		CREATIVE _____		
ITEM #:	2821915R1		MARKETING _____		
DIELINE #:	S170273				

SIZE: 1.031" X 1.031" X 3.500"		R&D _____
FILE NAME: RA_4XMEDICATED_TOOTHACHE_GEL_CTN_2821615R1-0LAI		QUALITY _____
PRINTER: MODPAC		PURCHASING _____
NOTE(S):		CEO _____
<small>NEW YORK OFFICE   1359 BROADWAY   17TH FLOOR   NEW YORK, NY 10018  TONAWANDA OFFICE   175 COOPER AVENUE   TONAWANDA, NEW YORK 14150</small>		

**Toothache & Gum Reliever**

20% Benzocaine to relieve oral pain

Antiseptic to kill harmful bacteria

Astringent to help prevent infection

Menthol to soothe gums

4x medicated

Oral antiseptic/pain reliever/astringent

Net Wt 0.25 oz (7g)

**4X MEDICATED SEVERE TOOTHACHE AND GUM GEL**

benzocaine gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-0615
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
<b>ZINC CHLORIDE</b> (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.5 g in 100 g
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y)	
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	

**Product Characteristics**

<b>Color</b>	blue	<b>Score</b>	
--------------	------	--------------	--

<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	WINTERGREEN	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0615-9	1 in 1 CARTON	05/06/2020	
1		7 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/06/2020	

**Labeler** - Rite Aid (014578892)

### Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(11822-0615)

Revised: 5/2020

Rite Aid